#15 Bill 1-24-01

JAN 23 2001

TECH CENTER 1600/2900

Assistant Commissioner
for Patents
Washington, D.C. 20231

TRAVERSAL AND REQUEST FOR RECONSIDERATION OF REQUIREMENT FOR RESTRICTION

Dear Sir:

Applicants, through their undersigned attorneys, hereby traverse and request reconsideration of the requirement for restriction set forth in the Official Action dated November 8, 2000 in the above-identified patent application. A shortened statutory response period of thirty (30) days was indicated in the November 8, 2000 Official Action. The initial due date for response, therefore, was December 8, 2000. A petition for a one (1) month extension of the response period is presented herewith.

The restriction requirement in this case is manifestly improper for failure to comply with 37 C.F.R. §1.475 and relevant provisions of the Manual of Patent Examining Procedure (M.P.E.P.).

The present application was filed under 35 U.S.C. §371 as a U.S. national stage application under the Patent Cooperation Treaty. Accordingly, the usual restriction practice applied under 35 U.S.C. §121 is inapplicable to the present application, as unequivocally stated in the follow passage from §1895.01, subparagraph D of the M.P.E.P.:

> Restriction practice in both international and national stage applications is determined under unity of invention principles as set forth in 37 C.F.R. §1.475 and 1.499. Restriction practice under 35 U.S.C. §121, as it applies to national applications submitted under 35 U.S.C. §111(a), is not applicable to either international or national stage applications...

According to 37 C.F.R. §1.475(a):

> Where a group of inventions is claimed in an application, the requirement of unity of invention shall be fulfilled only when there is a technical relationship among those inventions involving one or more of the same or corresponding special technical features. The expression "special technical features" shall mean those technical features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art.

The applicants respectfully submit that the subject matter of Groups I, IV, V and VI have unity of invention. The special technical feature linking the inventions is a pesticidal agent from *Xenorhabdus* which is active when administered orally.

Group I relates to a composition comprising a proteinaceous pesticidal agent from a *Xenorhabdus* species having activity when administered orally. It is noted in this connection that claims 13 and 14 (which are not addressed in the November 8, 2000, Official Action) are methods of using the composition of claims 1 to 12. As such, these claims are expressly permitted along with the corresponding product claim according to Annex B of the PCT administrative instructions.

Group IV relates to recombinant DNA encoding such a pesticidal agent, and as such can be considered as dedicated 'starting materials' in the production of the protein 'final product'. Thus the two groups are technically related, being linked by the special technical feature of this pesticidal agent.

Group V relates to a host DNA organism which comprises such a recombinant DNA. Organisms and methods to provide such organisms are known. Therefore the Groups IV and V are linked by the special technical feature of the recombinant DNA which

encodes the pesticidal agent.

Group VI relates to hosts other than plants comprising such DNA and has unity with group IV for the same reasons given for Group V.

The Examiner's citation of a prior art reference disclosing a toxin gene from *Xenorhabdus* that is patentably quite distinct from applicants' claims (as will be made clear in the discussion hereinbelow) clearly fails to establish lack of unity of invention in the present case. A review of the international proceedings reveals that the very same prior art reference cited by the Examiner, i.e. WO 95/00647, was listed in the international search report, and yet there was no lack of unity of invention objection during international proceedings. Given these circumstances, it should be evident that the present claims satisfy the above-quoted unity of invention principles set forth in 37 C.F.R. §1.475.

Moreover, it is further respectfully submitted that the novelty of claim 1 is not destroyed by WO 95/00647, notwithstanding the Examiner's assertion to the contrary. As noted above, claim 1 specifies that the insecticidal composition has toxic activity when administered orally. This special technical feature of oral administration is not disclosed in WO 95/00647. First of all, there is **no statement** at any point in WO95/00647 that *X. nematophilus* toxins can be used orally. Secondly, there is **no demonstration** in WO 95/00647 of a toxin which has oral activity. The comment in WO 95/00647, page 1, lines 16-19 that a nematode is not required must be interpreted in the light of the later paragraphs on page 4 and 5 which show

activity by injection. Thirdly, the Examiner has raised **no well-founded r asons to assume** that the WO 95/00647 toxins have oral activity.

Nor is there any *prima facie* reason to assume that all *Xenorhabdus* will have oral activity, and indeed the opposite is the case. Nematodes present in soil seek out an insect host, they then puncture through the insect surface and release (i.e. **inject**) *Xenorhabdus* bacteria into the insect's haemocoel. Thus in nature the *Xenorhabdus* bacteria need not have evolved to be active orally.

Inasmuch as the November 8, 2000 Official Action fails to comply with the applicable United States Patent and Trademark Office rules in setting forth the restriction requirement, for the reasons given above, it is respectfully submitted that the requirement should be reconsidered and withdrawn.

In order to be fully responsive, however, applicants hereby elect, with traverse, the Group I invention, i.e., the subject matter of claims 1-12. The subject matter of claims 13 and 14 should be examined with the Group I invention for the reason stated above.

Applicants reserve the right to file one or more continuing applications, as provided under 35 U.S.C. §120, on the subject matter of any claim ultimately held withdrawn from consideration in this application.

Early and favorable action on this application is respectfully requested.

Respectfully submitted,

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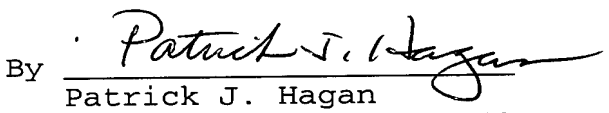
SKILLMAN, P.C.
Attorneys for Applicant

By 
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